

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 1, 2010. Currently, claims 9, 12, 16, 17, 19, 21-23, and 38-42 remain pending and have been rejected. Applicants note that claim 20 was previously canceled. With this communication, claim 39 is canceled. Favorable consideration of the following remarks is respectfully requested.

### **Drawings**

Claim 39 has been canceled rendering the objection to the drawings moot.

### **Claim Rejections – 35 USC § 112**

Claims 9 and 40 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites that the tip, disposed at the distal end of the elongate tubular member, has a tip lumen extending therethrough. This recitation further limits the structure of the tip by providing for the guidewire to exit the tip through a tip lumen as opposed, for example to exiting through the sidewall of the elongate tubular member proximal of the tip. Claim 40 addresses those embodiments in which the tip is integrally formed and disposed on the distal end of the elongate amorphous polymeric tubular member and similarly limits the claimed structures to those in which the guidewire exits through a tip lumen.

Accordingly it is believed proper to recite that the tip portion and/or the tip portion of the elongate member includes a guidewire lumen which allows the guidewire to interact with the distal end of the tip in the manner claimed, i.e., to invert proximally into the tip lumen upon engaging the distal stop. Further, it is believed that one of ordinary skill in the art would interpret the claims in this manner in view of the specification. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory

requirement. (MPEP 2173.02)

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. In this instance, both the body of the elongate tubular member and a tip portion associated with the elongate tubular member have guidewire lumens therethrough and both limitations have been properly recited. Applicants respectfully request that the rejection be withdrawn.

**Claim Rejections – 35 USC § 103**

Claims 9, 12, 16, 17, 19-23, 38, and 39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (U.S. Published Patent Application No. 2003/0125751), hereinafter Griffin, in view of Muni et al. (U.S. Patent No. 5,316,706), hereinafter Muni, and further in view of Van Tassel et al. (U.S. Patent No. 4,531,943), hereinafter Van Tassel. As noted above, claim 20 has previously been canceled. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03).

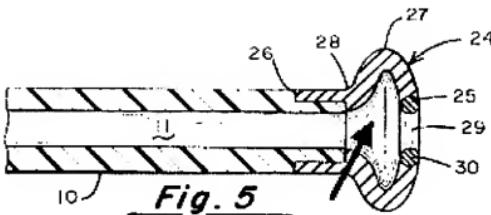
The Office Action acknowledges that Griffin does not disclose that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof or that the distal end of the tip is configured to invert proximally into the tip lumen upon engaging the distal stop. Indeed, the distal end of the tip 11 of Griffin appears necessarily to be incapable of engaging the distal stop 29 given the intervening tubular member 300 of filter 26. Omitting the filter 26 of Griffin to allow the tip to engage the distal stop would appear to render the device of Griffin unsatisfactory for its intended purpose of retrieving the filter 26 which, being disposed about the guidewire between the tip 11 and the stop 29, must always be present and thus must prevent the engagement recited in claims 9 and 40. (See MPEP § 2143.01 Part V.)

Muni is asserted to disclose a catheter in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections. The Office Action further asserts that Muni discloses that the crystallinity may be varied in any of a plurality of zones throughout the length; however it does not appear to be the case that Muni discloses a catheter having a crystalline tip distal end and an amorphous distal body. The disclosure of Muni appears to be limited to the crystalline/amorphous nature of the polymer of the catheter which appears to correspond generally to the elongate body. The pattern of crystallinity in the elongate body is immaterial to the claim. However, should the Office assert that the distal end of the catheter of Muni suffices to correspond to a “tip” of the catheter, it should be noted that Muni appears to disclose only embodiments in which the distalmost ends are amorphous thereby providing “a soft, pliable andatraumatic tip” while the more proximal regions include “stiff steerable and pushable catheters”. (Col. 3, lines 1-5.) Thus one of ordinary skill in the art would not be motivated to, while introducing additional crystallinity as taught by Muni, invert the general order of amorphous distal end and crystalline proximal region for the reason that the resulting catheter would appear to have the undesirable properties of a relatively more trauma inducing tip and a lack of stiffness, steerability, and pushability while being less resistant to kinking. (Col. 3, lines 44-49.)

Further, the catheter of Muni appears to be a single body, at least a portion of which is crystallizable, while it is not inherently the case that the amorphous material of tip of claim 9 is crystallizable by following the teaching of Muni. Claim 9 admits of embodiments in which the radially inextensible distal portion of the tip is a different, crystallizable material which is joined to the amorphous portion of the tip. Thus the combination of Griffin and Muni does not appear to disclose all features of claim 9.

The Office Action asserts that Van Tassel discloses a catheter in Figs. 4 and 5 such that “the shape of the distal tip of the catheter is such that when it contacts a surface it allows the distal end of the tip to invert proximally into the tip lumen”. Applicants respectfully disagree. Instead, the tip of Van Tassel appears to fold upon contact generally at the hinge location indicated by reference numeral 27. At no time does the extreme tip or end 25 of flexible plastic sleeve 24, also characterized as soft compressible tip member 24 or as a soft deformable tip member, appear to “invert proximally into the

tip lumen upon engaging the distal stop" as recited in claim 9. As will be seen in modified Fig. 5 reproduced below, "collapse to yield the configuration shown in Fig. 5" does not result in the distal tip inverting into the lumen (indicated by the bold arrow) of the tip. End 25 remains outside of the lumen of the tip.



Thus Van Tassel does not appear to overcome the deficiencies of Griffin and/or Muni and the combination does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. For the reasons discussed above and others, Applicants respectfully request that the rejection of independent claim 9 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 9, 12, 16, 17, 19, 21-23, 38, and 39, which depend from nonobvious independent claim 9, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 40-42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin in view of Muni and further in view of Van Tassel. After careful review, Applicant must respectfully traverse this rejection.

As noted above, omitting the filter 26 of Griffin to allow tip 11 to engage the distal stop 29 would appear to render the device of Griffin unsatisfactory for its intended purpose of retrieving the filter 26 which, being disposed about the guidewire between the tip 11 and the stop 29, must always be present and thus must prevent the engagement

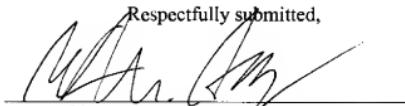
recited in claim 40. (See MPEP § 2143.01 Part V.) As also noted above, the arrangement of crystalline and amorphous regions taught by Muni would appear to be unsatisfactory for their intended purpose of providing a stiff pushable shaft having a soft atraumatic tip if reversed as suggested by the Office Action. Further still, the catheter of Muni does not appear to overcome the deficiencies of Griffin as discussed in detail above. The addition of Van Tassel does not appear to provide a tip "configured to invert such that the elastic portion folds back upon itself and the radially inextensible distalmost extremity is shifted proximally into the enlarged cavity upon engaging the distal stop" as recited in claim 40 and the disclosure of Van Tassel does not appear to overcome the inability of the distal stop of Griffin to contact the radially inextensible distalmost extremity of the tip or to do so in a manner such that the distalmost extremity is shifted proximally into the enlarged cavity of the tip. For at least these reasons, Griffin in view of Muni and Van Tassel does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. Applicants respectfully request that the rejection of independent claim 40 be withdrawn.

Additionally claims 41 and 42, which depend from nonobvious independent claim 40, are also believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

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Respectfully submitted,



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